

REMARKS

Reconsideration of the present application is respectfully requested.

Claims 34-80 are pending in the application.

Double Patenting Rejection

The examiner has rejected claims 34-73 of the instant application under 35 U.S.C. §101 as claiming the same invention as that of (i) claims 209-230 of allowed Application No. 10/127,817 ("the '817 application") and (ii) claims 209-224 of allowed Application No. 10/770,969 ("the '969 application," now U.S. Pat. No. 6,900,241 issued May 31, 2005). Applicants respectfully traverse the rejections for the reasons outlined below.

According to the MPEP Section 804 II A entitled "Statutory Double Patenting – 35 U.S.C. § 101" (see attached), the "[s]ame invention' means identical subject matter." When determining whether a statutory basis for a double patenting rejection exists, a reliable question to be asked is: "Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist" (see Section 804 II A, 2nd par.).

Rejection over the '817 application:

Following the instructions of the MPEP Section 804 II A, Applicants have compared each claim of the present application (claims 34-80) with each claim of the '817 application (claims 209-230) and in each situation identified embodiments within the scope of one claim but not within the scope of the other claim. Applicants' comparisons were based on the type of compounds being administered according to the respective methods of the compared claims (additional differences between the claims may therefore exist). The claims of the present application are grouped below based on the differences from the claims of the '817 application.

Claims 34-38, 41-45, 48-52, 55-59, and 62-70 of the present application recite methods of treatment or prophylaxis which comprise administration of compounds some

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of which compounds are not recited in the method claims of the '817 application. For example, a method of treatment/prophylaxis which comprises administration of a gallated procyanidin oligomer is an embodiment within the scope of the present claims 34-38, 41-45, 48-52, 55-59, and 62-70 but not within the scope of any of the method claims of the '817 application.

Claims 39, 40, 46, 47, 53, 54, 60, 61, 71-79 of the present application recite methods of treatment or prophylaxis which comprise administration the compounds different from the compounds recited in claims 209-216, 228 and 230 of the '817 application. For example, a method of treatment/prophylaxis which comprises administration of a compound having a sugar moiety at at least one carbon atom position C-4, C-6 or C-8 (see formula in claim 209 of the '817 application) is an embodiment within the scope of claims 209-216, 228 and 230 of the '817 application but not within the scope of the present claims 39, 40, 46, 47, 53, 54, 60, 61, 71-79.

Additionally, claim 80, which recites a method of treatment or prophylaxis which comprises administration of a glycosylated procyanidin oligomer is of a broader scope than the above mentioned claims 209-216, 228 and 230 of the '817 application.

Claims 34-80 of the present application recite methods of treatment or prophylaxis which comprise administration the compounds some of which are not recited in the method claims of the '817 application for reasons additional to those above. For example, a method of treatment/prophylaxis which comprises administration of a procyanidin dimer which contains at least one catechin unit as well as a method of treatment/prophylaxis which comprises administration of a procyanidin trimer which contains at least one catechin unit (and gallated and glycosylated compounds thereof) are embodiment within the scope of the present claims 34-80 but not within the scope of the method claims 217-221 and 229 of the '817 application.

Claims 34-80 of the present application recite methods of treatment or prophylaxis which are different from the methods recited in claims 222-227 of the '817 application. For example, none of the claims 34-80 require administration of a cocoa extract, cocoa extract fraction or cocoa-solids or liquor as required by claims 222-227 of the '817 application.

Referring to the above, each claim of the present application (claims 34-80) differs in scope from each claim of the '817 application (claims 209-230) by multiple embodiments. According to the MPEP Section 804 II A (attached), "same invention" double patenting does not exist. Withdrawal of the rejection is respectfully requested.

Rejection over the '969 application:

Claims 34-80 of the present applications recite methods of treatment or prophylaxis which comprise administration of oligomeric compounds (containing at least two monomeric units). In contrast, the methods of the claims 209-218 of the '969 application recite methods which comprise administration of monomeric compounds.

Claims 219-224 of the '969 application are drawn to *an article of manufacture* which is a different statutory subject matter than that recited in the claims of the present application.

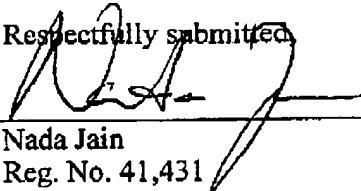
Therefore, none of the embodiments within the scope of the present claims fall within the scope of any of the '969 application claims. According to the MPEP Section 804 II A (attached), "same invention" double patenting does not exist. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above remarks, Applicants believe that the application is in condition for allowance. Such action is respectfully requested.

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Respectfully submitted,


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804 II A

RESTRICTION IN APPLICATIONS FILED UNDER 35 U.S.C. 111; DOUBLE PATENTING

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II. REQUIREMENTS OF A DOUBLE PATENTING REJECTION (INCLUDING PROVISIONAL REJECTIONS)

When a double patenting rejection is appropriate, it must be based either on statutory grounds or nonstatutory grounds. The ground of rejection employed depends upon the relationship of the inventions being claimed. Generally, a double patenting rejection is not permitted where the claimed subject matter is presented in a divisional application as a result of a restriction requirement made in a parent application under 35 U.S.C. 121.

Where the claims of an application are substantively the same as those of a first patent, they are barred under 35 U.S.C. 101 - the statutory basis for a double patenting rejection. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor" Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). Where the claims of an application are not the "same" as those of a first patent, but the grant of a patent with the claims in the application would unjustly extend the rights granted by the first patent, a double patenting rejection under nonstatutory grounds is proper.

In determining whether a proper-basis exists to enter a double patenting rejection, the examiner must determine the following:

(A) Whether a double patenting rejection is prohibited by the third sentence of 35 U.S.C. 121 (see MPEP § 804.01; if such a prohibition applies, a double patenting rejection cannot be made);

(B) Whether a statutory basis exists; and

(C) Whether a nonstatutory basis exists.

Each determination must be made on the basis of all the facts in the application before the examiner. Charts I-A, I-B, II-A, and II-B** illustrate the methodology of making such a determination.

Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. *In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964). However, the presence of domination does not preclude double patenting. See, e.g., *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

A. Statutory Double Patenting — 35 U.S.C. 101

In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? 35 U.S.C. 101 prevents two patents from issuing on the same invention. "Same invention" means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine." On the other hand, claims may be differently worded and still define the same invention. Thus, a claim reciting a widget having a length of "36 inches" defines the same invention as a claim reciting the same widget having a length of "3 feet."

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MANUAL OF PATENT EXAMINING PROCEDURE

If it is determined that the same invention is being claimed twice, 35 U.S.C. 101 precludes the grant of the second patent regardless of the presence or absence of a terminal disclaimer. *Id.*

Form paragraphs 8.30 and 8.31 (between an issued patent and one or more applications) or 8.32 (provisional rejections) may be used to make statutory double patenting rejections.

¶ **8.30 35 U.S.C. 101, Statutory Basis for Double Patenting "Heading" Only**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Examiner Note:

The above form paragraph must be used as a heading for all subsequent double patenting rejections of the statutory (same invention) type using either of form paragraphs 8.31 or 8.32.

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¶ **8.31 Rejection, 35 U.S.C. 101, Double Patenting**

Claim [1] rejected under 35 U.S.C. 101 as claiming the same invention as that of claim [2] of prior U.S. Patent No. [3]. This is a double patenting rejection.

Examiner Note:

1. This form paragraph must be preceded by form paragraph 8.30 and is used only for double patenting rejections of the same invention claimed in an earlier patent; that is, the "scope" of the inventions claimed is identical.

2. If the conflicting claims are in another copending application, do not use this form paragraph. A provisional double patenting rejection should be made using form paragraph 8.32.

3. Do not use this form paragraph for nonstatutory-type double patenting rejections. If nonstatutory type, use appropriate form paragraphs 8.33 to 8.39.

4. This form paragraph may be used where the conflicting patent and the pending application are:

- (a) by the same inventive entity, or
- (b) by a different inventive entity and are commonly assigned even though there is no common inventor, or
- (c) not commonly assigned but have at least one common inventor, or

(d) made as a result of activities undertaken within the scope of a joint research agreement.

5. In bracket 3, insert the number of the conflicting patent.

6. If the patent is to a different inventive entity and is commonly assigned with the application, form paragraph 8.27 should additionally be used to require the assignee to name the first inventor.

7. If evidence is of record to indicate that the patent is prior art under either 35 U.S.C. 102(f) or (g), a rejection should also be made using form paragraphs 7.15 and/or 7.19 in addition to this double patenting rejection.

8. If the patent is to a different inventive entity from the application and the effective U.S. filing date of the patent antedates the effective filing date of the application, a rejection under 35 U.S.C. 102(e) should additionally be made using form paragraph 7.15 (f).

¶ **8.32 Provisional Rejection, 35 U.S.C. 101, Double Patenting**

Claim [1] provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim [2] of copending Application No. [3]. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Examiner Note:

1. This form paragraph must be preceded by form paragraph 8.30 and is used only for double patenting rejections of the same invention claimed in another copending application; that is, the scope of the claimed inventions is identical.

2. If the conflicting claims are from an issued patent, do not use this paragraph. See form paragraph 8.31.

3. Do not use this paragraph for nonstatutory-type double patenting rejections. See form paragraphs 8.33 to 8.39.

4. This form paragraph may be used where the conflicting claims are in a copending application that is:

- (a) by the same inventive entity, or
- (b) by a different inventive entity and is commonly assigned even though there is no common inventor, or
- (c) not commonly assigned but has at least one common inventor, or

(d) made as a result of activities undertaken within the scope of a joint research agreement.

5. Form paragraph 8.28 may be used along with this form paragraph to resolve any remaining issues relating to priority under 35 U.S.C. 102(f) or (g).

6. In bracket 3, insert the number of the conflicting application.

7. A provisional double patenting rejection should also be made in the conflicting application.

8. If the copending application is by a different inventive entity and is commonly assigned, form paragraph 8.27 should additionally be used to require the assignee to name the first inventor.

9. If evidence is also of record to show that either application is prior art unto the other under 35 U.S.C. 102(f) or (g), a rejection should also be made in the other application using form paragraphs 7.15 and/or 7.19 in addition to this provisional double patenting rejection.

10. If the applications do not have the same inventive entity and effective U.S. filing date, a provisional 102(e) rejection should